Remarks/Arguments:

According to the Office Action, mailed June 24, 2004 (hereinafter, "Office Action"), claims 25 to 27 are currently pending and under examination. In the Office Action, the Examiner made the following new arguments, objections and rejections:

- Nonstatutory Double Patenting of Claims 25-27.
- Objection to Claim 25.
- Claim Rejections – 35 USC § 112, first paragraph (Written Description)
- Claim Rejections – 35 USC § 112, first paragraph (New Matter)

1. Remarks:

a. Response is timely.

A response to the Office Action is due on September 24, 2005. This response was filed before this date and is therefore timely.

b. Fees.

The Applicants attach hereto a completed Credit Card Payment Form in the amount of $1,202.00, the breakout of which is:

(1) $ 130.00 fee under 37 CFR 1.20(d) for the filing of a terminal disclaimer (statutory disclaimer),

(2) $790.00 fee under 37 CFR 1.17(e) for the filing of a Request for Continued Examination,

(3) $264.00 fee under 37 CFR 1.16(b) for adding three additional independent claims by amendment to the Instant Application, and

(4) $18.00 fee under 37 CFR 1.16(c) for adding 1 additional claim by amendment to the Instant Application.

The Applicants do not believe that any additional fees are due. However, please charge any additional fees required or credit any fees overpaid to Deposit Account No. 50-0244.

c. Amendments to the Claims.

Claim 25 was amended without prejudice or disclaimer and to further Applicants' business interests and the prosecution of the present application. The amendment to

claim 25 is supported by the specification at page 64, lines 6-14 (immunogenic composition comprising not more than one claimed peptide).

Claims 28-30 were added. These claims are supported by the specification at page 32, lines 6-9 (adjuvant) and at page 64, lines 6-14 (immunogenic composition comprising not more than one claimed peptide).

The amendments to the claims as discussed above do not add any new matter. Applicants reserve the right to prosecute any canceled or amended subject matter in a later application.

2. Arguments.

a. Nonstatutory Double Patenting of Claims 25-27.

Claims 25-27 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-3 of U.S. Patent No. 5,922,562 in view of Loosmore et al., WO 96/40929.

The Applicants attach hereto the appropriate terminal disclaimer. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

b. Objection to Claim 25.

Claim 25 was objected to for the informality that the claim refers to "...a pharmaceutically acceptable carrier therefor". The Examiner suggested that the phrase be made to read "...a pharmaceutically acceptable carrier thereof" and requested correction.

The Applicants amended claim 25 so that the phrase "...a pharmaceutically acceptable carrier therefor" now reads "...a pharmaceutically acceptable carrier thereof". Accordingly, the Applicants respectfully request that this objection be withdrawn.

c. Claim Rejections – 35 USC § 112, first paragraph (Written Description).

Claims 25-27 were rejected for lack of written description under 35 USC § 112, first paragraph. The Examiner alleged that:

(1) the specification provides no guidance as to what the upper limit of the number of synthetic peptides may be encompassed by the composition;

(2) the claims fail to limit the number of peptides and other components which may be within the composition because the composition recites open language and therefore includes a wide variety and unlimited number of additional components; and

(3) no specific limitations for what additional peptides or ingredients have been disclosed in the instant specification, and such unlimited addtions have not been taught and/or enabled by the specification.

Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

First, the Applicants respectfully submit that there are descriptive words in the specification which meet the written description requirement under 35 USC § 112, first paragraph, for the claimed immunogenic composition comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier thereof; wherein the synthetic peptide is comprised of the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85). The descriptive words are found at page 9, lines 28-32, of the Instant Application, which states:

> The immunogenic composition may comprise a plurality of active components to provide protection against disease caused by a plurality of species of transferrin receptor producing bacteria.

The term "active components" is defined at page 9, lines 7-16, which states, in pertinent part:

> In accordance with another aspect of the invention, an immunogenic composition is provided which comprises at least one active component selected from at least one nucleic acid molecule as provided herein, at least one recombinant protein as provided herein, at least one of the purified and isolated Tbp1 or Tbp2 proteins, as provided herein, at least one synthetic peptide, as provided herein, at least one purified and isolated truncated Tbp2 protein, as provided herein and a live vector, as provided herein... [underline added for emphasis]

Second, as the Applicants wish to further their business interests and the prosecution of the present application, claim 25 was amended, without disclaimer or prejudice, to recite:

> An immunogenic composition comprising not more than one synthetic peptide having no less than six amino acids and no more than 150 amino acids, and a pharmaceutically acceptable carrier thereof; wherein the synthetic peptide is comprised of the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85), and which produces an immune response when administered to a host.

By this amendment, claims 26 and 27 which depend on claim 25 are also both amended. This amendment further clarifies what the Applicants consider as one aspect of their invention; namely, the claimed immunogenic compositions. To this end, the Applicants have deleted the phrase "at least one" and replaced it with the phrase "not more than one" to clarify that the claimed immunogenic composition of claim 25 comprises: (1) one and only one member of the genus of synthetic peptides with an amino acid sequence comprising the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85) which have no less than six amino acids and no more than 150 amino acids; and (2) a pharmaceutically acceptable carrier thereof. Accordingly, the claimed invention is, for the purposes of the written description inquiry, that which is claimed in amended claims 25-27.

Third, the Applicants respectfully submit that they show possession of the claimed invention by describing it with all of its limitations using the words as a descriptive means that fully set forth the invention of amended claims 25-27. These words are found in the Instant Application at page 9, lines 7-19, which states:

> In accordance with another aspect of the invention, an immunogenic composition is provided which comprises at least one active component selected from at least one nucleic acid molecule as provided herein, at least one recombinant protein as provided herein, at least one of the purified and isolated Tbp1 or Tbp2 proteins, as provided herein, at least one synthetic peptide, as provided herein, at least one purified and isolated truncated Tbp2 protein, as provided herein and a live vector, as provided herein, and a pharmaceutically acceptable carrier therefor or vector therefor. The at least one active component produces an immune response when administered to a host. [underline added for emphasis]

which show that the claimed immunogenic composition is comprised of "at least one" of the peptides described. The words "at least one" certainly include within their scope the limitation of "not more than one" of the peptides described. Furthermore, the Applicants

point to the descriptive words found in the Instant Application page 64, line 9 through 14, of the Instant Application, which state:

> Guinea pigs were immunized intramuscularly with 100 μg of peptide, prepared as described in Example 16, emulsified in Freund's complete adjuvant on day 0 followed by boosters on days +14 and +28 using the same amount of peptide emulsified in Freund's incomplete adjuvant.

With respect to the "other components", "a wide variety and unlimited number of additional components" and other "ingredients" which the Examiner alleges can be included with the immunogenic composition, the Applicants respectfully submit that they have stated in the Instant Application words which would convey with reasonable clarity to those skilled in the vaccine arts the specific nature and limited number of such components and ingredients which could additionally be included in the claim immunological composition. At page 31, line 34 through page 32, line 36 of the Instant Application, the Applicants use the descriptive words:

> Immunogenic compositions including vaccines may be prepared as injectables, as liquid solutions or emulsions. The transferrin receptor, analogs and fragments thereof and/or peptides may be mixed with pharmaceutically acceptable excipients which are compatible with the transferrin receptor, fragments analogs or peptides. Such excipients may include, water, saline, dextrose, glycerol, ethanol, and combinations thereof. The immunogenic compositions and vaccines may further contain auxiliary substances such as wetting or emulsifying agents, pH buffering agents, or adjuvants to enhance the effectiveness of the vaccines. Immunogenic compositions and vaccines may be administered parenterally, by injection subcutaneously or intramuscularly. Alternatively, the immunogenic compositions formed according to the present invention, may be formulated and delivered in a manner to evoke an immune response at mucosal surfaces. Thus, the immunogenic composition may be administered to mucosal surfaces by, for example, the nasal or oral (intragastric) routes. The immunogenic composition may be provided in combination with a targeting molecule for delivery to specific cells of the immune system or to mucosal surfaces. Some such targeting molecules include strain B12 and fragments of bacterial toxins, as described in WO 92/17167 (Biotech Australia Pty. Ltd.), and monoclonal antibodies, as described in U.S. Pat. No. 5,194,254 (Barber et al). Alternatively, other modes of administration including suppositories and oral formulations may be desirable. For suppositories, binders and carriers may include, for example, polyalkalene glycols or triglycerides. Oral formulations may include normally employed incipients such as, for example, pharmaceutical grades of saccharine, cellulose and magnesium carbonate. These compositions take the form of solutions, suspensions, tablets, pills, capsules, sustained release formulations or powders and contain 10-95% of the transferrin receptor, fragment analogs and/or peptides. [underline added for emphasis]

Finally, in view of the above, the Applicants respectfully submit the amended claims 25-27 meet the written description requirement under 35 USC § 112, first paragraph. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

d. Claim Rejections – 35 USC § 112, first paragraph (New Matter).

Claims 25-27 were rejected as containing new matter as they fail to comply with the written description requirement of 35 USC § 112, first paragraph.

It has been shown above that the amended claims 25-27 meet the written description requirement of 35 USC § 112, first paragraph. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

3. Conclusions.

The amendments, remarks and arguments submitted herein are intended to be fully responsive to the outstanding Office Action, to advance the prosecution of the present invention, and to place the application in condition for allowance.

The Applicants respectfully request consideration and entry of this paper. The Applicants also respectfully request reconsideration of this application, as amended, and issuance of a timely Notice of Allowance in this case. Should the Examiner have any questions concerning this application, he/she is invited to contact the undersigned at (570) 839-5537.

Respectfully submitted,

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